

Remarks**1. Specification**

The examiner objected to the specification because of a reference, in the first paragraph on page 2, to a patent application filed after the filing date of this application. In the response to the previous office action, mailed January 22, 2003, the paragraph was amended in an attempt to correct the reference to a U.S. patent application. The unexpected observation “that placental bikunin was able to increase airway surface liquid osmolarity and mucociliary transport in animal models,” as stated in the first paragraph on page 2, was described in U.S. 09/441,966, filed November 17, 1999, as well as in the parent application, U.S. 09/218,913, filed December 22, 1998. The appropriate correction has now been made.

2. Claim Rejections – 35 U.S.C. § 102

The applicant acknowledges the examiner’s withdrawal of the rejection of claims 2, 6-9, and 25 under 35 U.S.C. § 102(b) as being anticipated by Kawaguchi et al.

Claims 2, 6-9, and 25 were rejected under 35 U.S.C. § 102(b), as being anticipated by Shimomura et al., U.S. patent no. 5,731,412. In particular, the examiner stated: “The reference is deemed anticipatory for the claimed subject matter because the cloned human hepatocyte growth factor activator [which allegedly has the same sequence as SEQ ID NO:1 in this application] is expressed in and isolated from COS cells (see Example 8). The glycosylation pattern is presumed to be identical in COS cells, which are the same cells used to produce the glycosylated bikunin of the instant application.”

In response, the applicant respectfully points out that the glycosylated bikunin described in this application was produced in CHO cells (see Examples 1 to 3)—not COS cells, as the examiner mistakenly asserted.

According to the Board of Patent Appeals and Interferences, “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In this case, claim 2 recites a glycosylated bikunin comprising “at least one sialic acid residue.” While Shimomura teaches a protein produced in COS cells, the instant specification describes glycosylated protein produced in CHO cells. There is no reason to expect that CHO cells and COS cells produce proteins with identical glycosylation patterns. Therefore, it is inappropriate to rely on the applicant’s specification as evidence that Shimomura inherently anticipates the claimed invention. In other words, the examiner has not provided “a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art,” as required under *Levy*. Therefore, the applicant respectfully requests withdrawal of the § 102 rejection.

3. Claim Rejections – 35 U.S.C. § 103

The applicant acknowledges the examiner’s withdrawal of the rejection of claims 15, 18-21, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Gentz et al. in view of Gribben et al. and Hotchkiss et al.

Claims 15, 18-21, and 26 were rejected under 35 U.S.C. § 103(a), as being unpatentable over Shimomura et al., U.S. patent no. 5,731,412, in view of Delaria et al. In particular, the examiner stated: “It would have been obvious for one of skill in the art at the time of the invention to produce the single Kunitz domains of Delaria et al. in the CHO culture system of Shimomura et al., with the intended use for testing each glycosylated domain for activity against human hepatocyte growth factor activator. One would have had a very high expectation of success in the venture.”

In response, the applicant respectfully points out that Shimomura teaches production of glycosylated protein only in COS cells (see Example 8)—not CHO cells, as the examiner mistakenly asserted.

According to the Federal Circuit, “The PTO bears the burden of establishing a case of *prima facie* obviousness. A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.” *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993). Moreover, “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” M.P.E.P. § 2143.03 (citing *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974)). In this case, Shimomura and Delaria, both individually and in combination, fail to teach or suggest all of the claim limitations (in particular, that the glycosylated monokunin comprises “at least one sialic acid residue”). For example, as discussed above, Shimomura does not inherently teach sialic acid modification; Delaria does not address glycosylation at all. Accordingly, a *prima facie* case of obviousness has not been established. Therefore, the applicant respectfully requests withdrawal of the § 103 rejection.

4. Conclusion

In view of the amendments and remarks above, the application is considered to be in good and proper form for allowance. Therefore, the Patent Office is respectfully requested to pass the application to issue. If, in the opinion of the examiner, a telephone conference would expedite the prosecution of this application, the examiner is invited to call the undersigned attorney.

Respectfully submitted,

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